

REMARKS

Claims 1, 3-10, 12-15 and 17-49 are pending in this application. Claims 2, 11 and 16 have been canceled without prejudice or disclaimer. Claims 4-7, 10 and 20-48 have been withdrawn as being directed to non-elected subject matter. Claims 1, 3, 8-9, 12-15 and 17-19 have been amended. Claims 49-50 has been newly added.

Claims 2, 11 and 16 have been canceled without prejudice or disclaimer, and claims 1, 3, 8-9, 12-15 and 17-19 have been amended, for the sole reason of advancing prosecution. Applicants, by canceling or amending any claims herein, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert any of the claims canceled herein or the original claim scope of any claim amended herein, in a continuing application.

Claim 1 has been amended to recite “[a] system for minimally invasive breast lifting, comprising: one or more anchors adapted to be fixed to a posture tissue above a desired nipple level; two or more readily adjustable suspension members suspended from the one or more anchors each readily adjustable suspension member having a free end; and a cradling portion having a first end and a second end and being configured to cradle the breast from below, the first end and the second end of the cradling portion being integral with and/or movably attached to the free end of a respective suspension member[[s]], and having a width greater than the width of each of the two or more readily adjustable suspension members.” Support for claim 1, as amended, can be found throughout the specification and claims as originally filed.

Claims 3, 8-9, 12-15 and 17-19 depend, either directly or indirectly, from claim 1.

Claims 3, 8-9, 12-15 and 17-19 have been amended to be in a form consistent with U.S. practice.

Claim 49 has been newly added. New claim 49 is directed to “[a] system for minimally invasive breast lifting, comprising: one or more anchors adapted to be fixed to a posture tissue above a desired nipple level; two or more readily adjustable suspension members having an anchoring end, and a cradling end, the two or more readily adjustable suspension members being suspended from the one or more anchors at the anchoring end and being movably attached or fixed to the one or more anchors; a cradling portion having a first end movably attached or fixed to the cradling end of one of the two or more readily adjustable suspension members, and a second end movably attached or fixed to the cradling end of one of the two or more readily adjustable suspension members the cradling portion being configured to cradle the breast from below and having a width greater than the width of each of the two or more readily adjustable suspension members.” Support for new claim 49 can be found throughout the specification and claims as originally filed.

Claim 50 has been newly added. New claim 50 is directed to “[a] system for minimally invasive breast lifting, comprising: one or more anchors adapted to be fixed to a posture tissue above a desired nipple level; at least one readily adjustable suspension members having at least one an anchoring point, and at least one a cradling point, the at least one readily adjustable suspension members being suspended from the one or more anchors at the at least one anchoring point and being movably attached to and/or integral with the one or more anchors; a cradling portion having a first end movably

attached to and/or integral with the at least one cradling point of one of the at least one readily adjustable suspension members, and a second end movably attached to and/or integral with the cradling end of one of the at least one readily adjustable suspension members the cradling portion being configured to cradle the breast from below and having a width greater than the width of each of the two or more readily adjustable suspension members." Support for new claim 50 can be found throughout the specification and claims as originally filed.

No new matter has been added.

In view of the remarks set forth below, further and favorable consideration is respectfully requested.

- I. *At page 2 of the Official Action, claims 1, 3, 9, 12-15 and 17-19 have been rejected under 35 USC § 102(b) as anticipated by or, in the alternative, under 35 USC § 103(a) as obvious over Vijil-Rosales (US Patent No. 4,372,293) in view of Bellity (FR Patent No. 2746298) or Dessart (FR Patent No 22682284).*

The Examiner asserts that Vijil-Rosales, Bellity and Dessart either anticipates and renders claims 1, 3, 9, 12-15 and 17-19 obvious.

In view of the remarks set forth herein, this rejection is respectfully traversed.

The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131.

The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

To establish a *prima facie* case of obviousness, the Examiner must satisfy three requirements. First, as the U.S. Supreme Court very recently held in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), “a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” (*KSR*, 550 U.S. 398 at 417.) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Regarding motivation to modify properly combined references, **MPEP 2143** states that where the prior art conflicts, all teachings must be considered and that the fact that references can be combined or modified is not sufficient to establish *prima facie* obviousness. **MPEP 2143** further states that there must be some suggestion or motivation to modify the references, and there must be a reasonable expectation of success.

MPEP 2143.01 states that a proposed modification cannot render the prior art unsatisfactory for its intended purpose. If it does, then there is no suggestion or motivation to make the proposed modification. Further, the proposed modification cannot change the principle operation of a reference.

Applicants respectfully submit that the cited reference does not teach or suggest each and every element of the present claims as required for anticipation under 35 USC § 102 (b). Additionally, it is submitted that a *prima facie* case of obviousness has not been established because nothing in the applied references teach or suggest all of the elements of the present claims, as required by *In re Wilson*. Further, assuming *arguendo* that all of the elements were taught or suggested, Applicants respectfully submit that there is no motivation to modify the cited references to arrive at the presently claimed subject matter.

Independent claim 1 is directed to a system for minimally invasive breast lifting, comprising: one or more anchors adapted to be fixed to a posture tissue above a desired nipple level; two or more readily adjustable suspension members suspended from the one or more anchors each readily adjustable suspension member having a free end; and a cradling portion having a first end and a second end and being

configured to cradle the breast from below, the first end and the second end of the cradling portion being integral with and/or movably attached to the free end of a respective suspension member[[s]], and having a width greater than the width of each of the two or more readily adjustable suspension members. Claims 3, 9, 12-15 and 17-19 depend, either directly or indirectly, from claim 1.

Applicants respectfully note that the presently claimed subject matter is directed to a system for supporting and lifting a breast in a controlled manner. The system comprises a cradling portion for supporting a breast from below having adjustable suspension members integral with or movably attached to the ends of the cradling portion. As claimed the cradling portion has width greater than that of the suspension members. Additionally, the present claims recite one or more anchors adapted to be fixed to a posture tissue above a desired nipple level, and from which the adjustable suspending members are suspend. According to certain embodiments of the present subject matter, the adjustable suspending members may be controllably loosened or tensioned so as to achieve a desired form and position of the breast. The system is therefore configured to support and lift the breast.

In addition, the presently claimed system may be inserted and/or adjusted while a patient is positioned in an upright position under local anesthesia. Therefore, an actual indication regarding the breast's new form, its pertness and position may be achieved and evaluated by a doctor or patient in real time, under the forces of gravitation.

In contrast to the presently claimed subject matter, Vijil-Rosales is directed to an apparatus for the surgical correction of ptosis of the breast and a method of surgery for implementing such an apparatus. Vijil-Rosales describes a ribbon of inert mesh connected between the mammary gland and the clavicle, or other element of the skeletal structure above the breast. See Vijil-Rosales at the abstract. Additionally, Vijil-Rosales describes a device with a ***unitary*** width and ribbon-like shape, which is surgically attached, e.g., sutured, at its lower end to the mammary gland at least at one point. Applicants note that according to Vijil-Rosales a plurality of strands are required to achieve the purpose of the device because, according to Vijil-Rosales, the use of one strand or ribbon would not be able to withstand the forces exerted by the weight of the breast and the mechanical integrity of the strands may be damaged. See Vijil-Rosales at page 3, lines 18-19. In addition, the apparatus is made of a mesh so as to allow interweaving of the tissue with the mesh which is an imperative feature of the invention disclosed in Vijil-Rosales. See *Id.* at page 3, lines 62-64.

However, unlike the presently claimed subject matter, Applicants submit that Vijil-Rosales does not teach or suggest ***one or more anchors***, two or more ***readily adjustable suspension members***, or a cradling portion ***having a width greater than the width of each of the two or more readily adjustable suspension members*** and being ***integral with and/or movably attached to the free end of a respective suspension member***, within the meaning of present claim 1. (Emphasis added).

Unlike the presently claimed subject matter, Vijil-Rosales merely describe a ribbon of mesh connected between the mammary gland and the clavicle to support a breast. However, the ribbon of mesh described in Vijil-Rosales does not include one or

more anchors, as presently claimed. In contrast, the ribbon of mesh described in Vijil-Rosales is connected to the clavicle, or other skeletal tissue, via a surgical technique. Further, Vijil-Rosales does not teach or suggest two or more readily adjustable suspension members, as recited in present claim 1. In addition, Vijil-Rosales does not teach or suggest a cradling portion ***having a width greater than the width of each of the two or more readily adjustable suspension members*** and being ***integral with and/or movably attached to the free end of a respective suspension member.*** Therefore, the presently pending claims are neither anticipated nor rendered obvious by Vijil-Rosales.

With regard to the Examiner's assertion, at page 3 of the Official Action, that "the mesh would [be flattened] under the breast and be laterally compressed under the tension of suspending the breast," Applicants respectfully note that based on the structure of the device disclosed in Vijil-Rosales and the science of physics, it would appear that the mesh would actually be stretched below the weight of a suspended breast and ***not*** flattened (or laterally compressed) upon the weight of the breast. Therefore, there is no evidence that the mesh described in Vijil-Rosales would be wider below the breast at any point. However, should the Examiner choose to maintain this rejection on these grounds, Applicants respectfully request that the Examiner provide a reference, or an indication of authority grounded in physics, that the specific mesh described by Vijil Rosales would actually deform as asserted by the Examiner.

Bellity does not remedy the deficiencies of Vijil-Rosales. Bellity is directed an internal prosthesis for retaining an organ position and shape in the human body. The prosthesis of Bellity includes a girdle to at least partially enfold the organ and a means

for fixing the girdle inside the body. See Bellity at the abstract. The device described in Bellity is an under the skin pre shaped, bra-like device that is implanted around the breast tissue such that it substantially envelops and masks it. The top front portion of the device is affixed to the collar-bone of the patient. In order to allow the nipple to protrude for functions such as breast feeding, the device has to be provided with an opening for a nipple and areola, as it substantially envelops the breast tissue. See Bellity at Figure 3. Applicants note that the implantation procedure for the device described in Bellity would appear to require a severe and invasive surgical procedure that must be carried out with the patient under general anesthesia.

However, like Vijil-Rosales, Bellity does not teach or suggest two or more ***readily adjustable suspension members***, or a cradling portion ***having a width greater than the width of each of the two or more readily adjustable suspension members*** and being ***integral with and/or movably attached to the free end of a respective suspension member***, within the meaning of claim 1. In addition, Applicants note that both the structure and function described in Bellity differ from the present subject matter for at least the reason that, according to the present subject matter, the cradling portion embraces the breast tissue from below and breast lift is achieved by tensioning/releasing the respective suspension members in a controlled manner. Neither Vijil-Rosales nor Bellity describe a device that allows any controlled modification of the breast shape by tensioning/releasing of the suspending members. Therefore, whether taken alone, or in combination, the cited references do not teach or suggest each and every element of the presently pending claims.

Dessart does not remedy the deficiencies of Vijil-Rosales and Bellity. Dessart is directed to a mammary prosthesis capable of being incorporated under the skin of a patient, and arranged to restore the shape of and support the patient's breast. The prosthesis described in Dessart has a collar in the form of a flexible lamina. See Dessart at the abstract. Dessart describes a prosthesis device adapted to restore and support the patient's breast. The prosthesis described in Dessart has a shape of a collar which is adapted to envelope the mammary gland so as to form a pendulous shape. The collar is formed with two asymmetrical branches arranged to be able to touch each other and to be attached to each other when implanted around the breast. Implantation of the device described in Dessart requires a complete cutaneous incision around the breast and separation of the skin from the entire area of the breast. See Dessart, for example, at the abstract.

However, like Vijil-Rosales and Bellity, Dessart does not teach or suggest two or more ***readily adjustable suspension members***, or a cradling portion ***having a width greater than the width of each of the two or more readily adjustable suspension members*** and being ***integral with and/or movably attached to the free end of a respective suspension member***. Therefore, whether taken alone, or in combination, the cited references do not teach or suggest every element of the presently pending claims.

With specific regard to obviousness, Applicants submit that assuming *arguendo* each and every element of the presently claimed subject matter were taught or suggested by the cited art, any *prima facie* case of obviousness would be destroyed as there is no motivation to modify the cited references to arrive at the presently claimed

subject matter. In this regard, Applicants respectfully note that none of the references suggest that the modification of the devices disclosed therein would be aided by another device disclosed in a separate and different reference. In addition, Applicants submit that there is no motivation to modify the cited references because doing so would change the principle of operation of each the references. In this regard applicants note that none of the cited references operate with one or more anchors, two or more readily adjustable suspension members being integral with and/or movably attached to the free end of a respective suspension member and a cradling portion having a width greater than the width of each of the two or more readily adjustable suspension members. In addition, the devices disclosed in the cited references require stitching to tissue and/or surgical techniques not required by the presently claimed subject matter. Accordingly, modifying the cited references to arrive at the presently claimed subject matter would change the principle of operation of the references.

Accordingly, Applicants submit that none of the cited references anticipate, or render the presently claimed subject matter obvious, within the meaning of either of 35 USC §§ 102(b) or 103(a). Thus, the Examiner is respectfully requested to withdraw this rejection of claims 1, 3, 9, 12-15 and 17-19.

II. At page 3 of the Official Action, claim 8 has been rejected under 35 USC § under 35 USC § 103(a) as obvious over Vijil-Rosales in view of Bellity or Dessart.

The Examiner asserts that it would have been obvious to substitute the hook anchor of Bellity for the anchor of Vijil-Rosales on the system of Vijil Rosales in order to anchor the system.

Applicant respectfully traverses this rejection because a *prima facie* case of obviousness has not been established.

A brief outline of relevant authority is set forth above.

It is submitted that a *prima facie* case of obviousness has not been established because nothing in the applied references teach or suggest all of the elements of the present claims, as required by *In re Wilson*. Further, assuming *arguendo* that all of the elements were taught or suggested, Applicants respectfully submit that there is no motivation to modify the cited references to arrive at the presently claimed subject matter.

Independent claim 1 is discussed above with regard to the previous rejection. Claim 8, depends from independent claim 1. Accordingly, claim 8 is novel and non-obvious for at least the reasons set forth above with regard to the previous rejection.

The above discussions of each of the cited references are incorporated herein.

As discussed, whether taken alone or in combination, none of the cited references teach or suggest ***one or more anchors***, two or more ***readily adjustable suspension members***, or a cradling portion ***having a width greater than the width of each of the two or more readily adjustable suspension members*** and having a first end and a second ***movably attached to and/or integral with the free end of a respective suspension member***, within the meaning of claim 1. Therefore, whether taken alone, or in combination, the cited references do not teach or suggest every element of the presently pending claims.

In addition, as discussed above there is no motivation to modify the cited references to arrive at the presently claimed subject matter. In this regard, Applicants reiterate that there is no suggestion to do so and modifying the cited references would change the principle of operation described in the references.

In view of the remarks set forth herein, it is submitted that, whether taken alone or in combination, the cited references do not render the presently claimed subject matter obvious within the meaning of 35 USC § 103 (a). Accordingly, the Examiner is respectfully requested to withdraw this rejection of claim 8.

III. New Claims 49 and 50

Claims 49 and 50 have been newly added.

New claim 49 is directed to a system for minimally invasive breast lifting, comprising: one or more anchors adapted to be fixed to a posture tissue above a desired nipple level; two or more readily adjustable suspension members having an anchoring end, and a cradling end, the two or more readily adjustable suspension members being suspended from the one or more anchors at the anchoring end and being movably attached or fixed to the one or more anchors; a cradling portion having a first end movably attached or fixed to the cradling end of one of the two or more readily adjustable suspension members, and a second end movably attached or fixed to the cradling end of one of the two or more readily adjustable suspension members the cradling portion being configured to cradle the breast from below and having a width greater than the width of each of the two or more readily adjustable suspension members.

New claim 50 is directed to a system for minimally invasive breast lifting, comprising: one or more anchors adapted to be fixed to a posture tissue above a desired nipple level; at least one readily adjustable suspension members having at least one an anchoring point, and at least one a cradling point, the at least one readily adjustable suspension members being suspended from the one or more anchors at the at least one anchoring point and being movably attached to and/or integral with the one or more anchors; a cradling portion having a first end movably attached to and/or integral with the at least one cradling point of one of the at least one readily adjustable suspension members, and a second end movably attached to and/or integral with the cradling end of one of the at least one readily adjustable suspension members the cradling portion being configured to cradle the breast from below and having a width greater than the width of each of the two or more readily adjustable suspension members.

Applicants respectfully submit that new claims 49 and 50 are both novel and non-obvious. Accordingly, Applicants respectfully request an indication that all of the pending claims are now allowable.

CONCLUSION

In view of the foregoing, Applicant submits that the application is in condition for immediate allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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Date: March 3, 2009
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